K002137

OCT - 5 2000

Subscribers Name & Address:

Siemens-Elema AB
Electromedical Systems Division, ECS
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Official Correspondent: Dave Simard
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Trade Name:

Device name: **CATHCOR Desktop**

Common name, Classification number, Class & Regulation Number:

Common Name	*Classification Number*	*Class*	*Regulation Number*
Physiological Measurement and Display System	DQK	II	870.1425

Predicate Device Identification:

Legally marketed devices to which equivalence is being claimed	*510(k) #*
CATHCOR	K920587
EPCOR	K930786
MAC-Lab	K895801
MAC-Lab	K935394

Device Description (for detailed description see Section F):

The CATHCOR Desktop is a new Computerized Physiological Measurement and Display System to be used for the measurement, display, and printout of biophysiological events. Hemodynamic, and optional electrophysiologic signals, such as intracardiac pressure, ECG, and ICEG signals are measured and displayed by the system; a number of hemodynamic calculations are performed based on the measured values of the input signals. These data can be recorded in real-time on the hard drive and later printed on the laser printer. CATHCOR Desktop provides a number of hemodynamic calculations, and it has a capacity to store and report catheterization procedure data.

Intended Use of the Device:

The CATHCOR Desktop is a computer-based system for the measurement, display, and printout of biophysiological events.

Hemodynamic and electrophysiological signals such as intracardiac pressure, ECG and signals are measured and displayed, and a number of hemodynamic calculations are performed based on the measured values of the input signals. These data can be recorded in real-time and stored on a removable media.

A database on the computer hard disk is capable of storing catheterization procedure data input by the user, as well as data calculated by the system. The system can perform a number of administrative functions such as database searches and inventory management in order to support and maximize departmental efficiency.

The CATHCOR Desktop is able to communicate with external devices such as patient monitors for additional vital signs such as SpO_2, NIBP, Resp, Cardiac Output, etc.
The CATHCOR Desktop is also able to communicate with angio systems for bi-directional communication of patient demographics and is able to store angio information such as dose, gantry position, etc in the patient file in the database.
The CATHCOR Desktop is able to bi-directionally communicatewith external databases used for hospital information systems and cardiology data management systems.

Reports can be printed on a laser printer.

Summary of technological characteristics of Device and Predicate Device:

	Substantial Equivalent Devices		New Device
	CATHCOR	MAC-Lab	CATHCOR Desktop
Manufacturer	Siemens-Elema AB	Marquette	Siemens-Elema AB
510(k) Number	K920587/K930786	K895801/K935394	To be determined
Intended Use			
Intended Population	The CATHCOR system is intended to be used on adult and pediatric populations.		Same
Intended Environment	The system is intended for use in a cardiac catheterization laboratory, where pressure signals, ECG, and optional ICEG need to be monitored and recorded.		Same
Signal Inputs	12 lead ECG 4 pressure 4 universal		Same
Signal Outputs	2 analog 1 QRS trigger pulse		Same
Display Monitor	Color (CRT)		Same (CRT/Flat Screen)
Computing Environment Host Computer Operating System Networking Database User Interface	 Siemens PC UNIX Yes Yes Keyboard Mouse Menus		Same
Calculations Summary Heart Rate Arterial Pressures Atrial, Venous Press. Ventricular Pressures Pressure Gradients Oxygen Saturation Valve Area Cardiac Output (Fick) Stroke Wk., Pwr., Vol. Vascular Resistances Shunts dP/dt Regurgitation Fraction	Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes		Same
Support for ICEG input	12 channel via EPCOR		Same
ICEG signals available on analog output	Yes		Same
Manual measurement calipers support		Yes	Same
Support for recording of waveform data		Yes	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 5 2000

Mr. Dave Simard
Director, Quality Assurance and Regulatory Affairs
Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923

Re: K002137
Trade Name: CATHCOR Desktop
Regulatory Class: II (two)
Product Code: DQK
Dated: May 31, 2000
Received: July 14, 2000

Dear Mr. Simard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002137

Device Name: CATHCOR Desktop

Indications For Use:

The CATHCOR Desktop is a Physiological Measurement and Display System indicated for use by trained healthcare professionals on adult and pediatric patients in a cardiac catheterization laboratory, where pressure signals, ECG, and optional ICEG need to be monitored and recorded.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002137

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)